PRESCRIPTION OF GENERIC DRUGS: IMPACT ON PHARMA MARKETING, DISPENSATION OF MEDICINES & SOCIAL GOOD

SYNOPSIS SUBMITTED

by

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DECLARATION

I hereby declare that the synopsis entitled **"Prescription of Generic Drugs: Impact on Pharma Marketing, Dispensation of Medicines and Social Good"**is my own original work and it has not formed the basis for the award of any degree, diploma, associateship or fellowship of similar other titles.

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INTRODUCTION

Doctors play an important role in prescribing medicines for the treatment of medical illness of patients. Prescribing branded medicines or by generic names is the decision of a doctor. Generic medicines (or generic drugs) are cost-effective. Generic prescribing is being promoted in many countries to reduce the cost of treatment. Doctors in India are being directed by the government to prescribe generic medicines which doesn't seem to be going well with them due to several factors.

Generic medicines (copies of brand-name medicines) are those which are manufactured by companies other than the original innovator company and introduced in the market after expiry of the patent. World Health Organization (WHO) has defined the commonly understood terms "generic drug" or "generic medicine" meaning a pharmaceutical product which does not require an authorization from an innovator company to manufacture and is marketed after the patent has expired. Generic medicine is usually intended to be interchangeable with an original innovator product [21, 27].

There is only one generic name for each medication but several brands available as substitute to each other. The brand name is usually the largest writing on the packet. Augmentin, for instance, is the brand name for the generic medication amoxicillin plus clavulanic acid. Generic medicines are exactly the same in pharmacological effects as their brand-name counterparts meaning they have exactly the same strength, dosage, route of administration, intended use, effects, side-effects, safety and risks as the innovator product. For example, for popular branded medicines like Crocin and Calpol, their generic name is paracetamol.

Prices of pharmaceutical bulk drugs and formulations are fixed by National Pharmaceutical Pricing Authority (NPPA), an independent body of experts. As per the Revised Schedule – 1 based on National List of Essential Medicines, 2015, till June 2018, 851 medicines including 4 medical devices are regulated. Price approval for non-scheduled drugs (drugs not under direct price control) is not required. For scheduled (controlled) drugs 16% margin to wholesaler and retailer is fixed whereas for non-scheduled formulations the margin to be decided is left to the companies [14, 16, 17, 18].

Price comparison of some of the leading brands and its generic alternative from the government of India is given below:

	BRANDS			GENERCIS			
	Brand Name	**Company Name**	**Price MRP (Rs)**	**Generic Name**	**Company Name**	**Price MRP (Rs)**	**Price Diff. % (app.) Generic vs Brand**
Anti-infective	Augmentin	GSK	18.88 per tablet	Amoxycillin 500mg and Clavulanic acid 125mg	BPPI	8.71 per tablet	**↓54%**
	Ceftum	GSK	98.00 per tablet	Cefuroxime Axetil 500mg film coated tablet	BPPI	10.45 per tablet	**↓89%**
Antidiabetic	Glycomet	USV	1.58 per tablet	Metformin 500mg tablet	BPPI	0.40 per tablet	**↓75%**
	Huminsulin	Eli Lilly	148.00 per inj.	Insulin Injection IP 40 IU / ml inj.	BPPI	68.00 Per inj.	**↓54%**
Drugs for central nerve system	Pregacip M	Cipla	13.50 per capsule	Pregabalin 75mg + Methylcobalamin 750 mcg Tablet	BPPI	2.80 per capsule	**↓79%**
	Tegretol	Novartis	1.14 per tablet	Carbamazepine 200 mg tablet	BPPI	0.70 per tablet	**↓39%**
Drugs for cardio vascular system	Cilacar	JB Chemicals	12.81 per tablet	Cilnidipine 20 mg tablet	BPPI	1.80 per tablet	**↓86%**
	Olmesar	Macleods	9.65 per tablet	Olmesartan 20mg tablet	BPPI	1.33 per tablet	**↓86%**

Source of information: Online pharmacies & Jan Aushadhi

In a market survey conducted at Dehradun in May 2018 on price comparison between brands and generic for a leading antibiotic – amoxicillin plus clavulanic acid (amongst the top 10 most prescribed products) show that generic version is cheaper by 52% as detailed below. Interestingly, as per the feedback from few chemists, Brand – Novaclav is not being promoted to doctors but being offered at huge discounts to chemists.

Composition	Amoxycillin and Potassium Clavulanate Tablets 625mg (Amoxycillin 500mg and Clavulanic acid 125mg)			
Company Name	GSK	Micro Labs	Cipla	IDPL for BPPI (Jan Aushadhi)
Brand Name / Generic	**Augmentin** (research product of GSK)	**Bactoclav**	**Novaclav** (Being pushed by chemists as generic)	**Generic** (No Brand Name)
Price per tab (Rs)	18.88	18.26	18.88	8.71
Promotion	To Doctors	To Doctors	To Chemists (with heavy discounts)	Jan Aushadhi stores
Availability	At Chemists	At Chemists	At Chemists	At Jan Aushadhi Stores

Generic drugs sold under different brand names classified as 'Branded Generics' dominate the Indian pharmaceuticals market. The branded generic medicines are promoted to doctors for their support in getting prescriptions and are priced higher than the generics (without any brand name) sold through Jan Aushadhi stores. However, there are pharmaceutical companies who are not promoting some of the branded generic medicines to doctors but offering to chemists (or pharmacists) at huge discounts making it attractive for them to push or substitute as generics.

One prime reason to popularize generic medicine by the government is to make medicines affordable for people, who otherwise cannot afford expensive branded medicines. The role of generic medicines in reducing the healthcare expenditure has been recognized for a long time. Multiple studies have confirmed that savings in the range of 9 to 89% can be achieved in developing countries through substitution of originator brands by cheaper generic medicines [6].

Out-of-pocket payments were estimated at 62% of total health expenditure in 2014 in India where according to a survey, only 15% of the population is covered by health insurance, healthcare expenses are borne by 85% of Indians who pay out of their own pockets [26]. Almost all the countries in the world, rich or poor, are taking more interest with the rising healthcare costs. Branded generics dominate Indian market. Approximately 80% of medicines are off-patent sold under brand names by pharmaceutical companies. Branded generics are available

at high prices leading to affordability issues. As it is, more than 66.5% of India's population lives in the rural areas [23], out of which around 37% is either below the poverty line or close to it. According to a WHO report, a majority of Indian population (nearly 68%) has either inadequate availability or no access to essential medicines. Additionally, free medicine's availability in public healthcare services has dropped from 31.2% to 8.9% for inpatient and from 17.8% to 5.9 % for outpatient over the last two decades, according to a 2011 Public Health Foundation of India (PHFI) study.

The Centre's directive towards a legal framework to make doctors prescribe generic drugs followed by advisories issued by Medical Council of India asking physicians to 'as far as possible prescribe generic drugs' has failed to gather full support of doctors mostly in the private sector. Doctors so far seem unwilling to prescribe generic or unbranded chemical names of drugs.

There are numerous challenges with generic medicine prescription. The challenges obstructing popularity of generic medicines are due to several factors related to general population, chemists, prescribers, regulations and marketing of branded medicines by pharma companies which are detailed in the literature review.

LITERATURE REVIEW

Time to time the significance of prescribing generic medicines has been highlighted, largely to bring down the cost of medicines.

Use of generic medicines considerably brings down the cost of medicines to both governments and patients (WHO 2016) due to increase in competition, hence result in huge cost-savings. Under pharma regulation and WHO pre-qualification criteria, bioequivalence studies demonstrate the effectiveness of generic medicines.

A narrative review of 20 identified studies (18 in developed economies, only 2 in developing economies excluding India) on perception of consumers towards generic medicines was conducted globally from 1970 to 2008 (Hassali et al 2009). In general, mixed reactions were seen by the consumers which was due to divergence of views because of several factors such as country development level, consumers' socioeconomic background, medicine reimbursement scheme, government policy, relations with doctors, experience with medicines

in the past, and severity of illness. Further studies mostly in developing countries including the decision making processes for generic medications were needed where savings in cost are required more than in developed nations.

Increase in display of knowledge and confidence towards generic drugs has been observed over the years, especially in developed countries. Interventions contributing to increase in usage of generic medicines were seen as mass education, financial incentives, and larger communication between health care professionals and patients.

In the perspective of developing nations, in a study conducted in Brazil, the authors estimated 3.9% share of generics to total medicines. 86% of population knew generic drugs cost less and 70% knew quality is comparable to branded medicines, only 57% knew any packaging appearances that differentiates generic drugs from brands (Bertoldi et al 2005). Medical prescription and price are the most important factors in choosing medicines as concluded by the authors, a majority of patients bought exactly what was prescribed.

In another study on literature review of 53 studies for the period 1990 – 2013 from Europe (24), North America (10), Asia (6), Australia and New Zealand (5), Middle East (5), and one each from Africa, Latin America, and the Caribbean region showed that patients are unlikely to favour generics over branded medicines. Insufficient knowledge about unbranded medicines is common amongst larger proportion of patients and customers in many countries. Thus, patients need to be educated about unbranded medicines. The literature review also shows that in the promotion of generic medicines and generic substitution, physicians and pharmacists have an important role to play in educating patients (Alrasheedy et al 2014).

Education by doctors and chemists appear to be the best method to promote generic drugs to medicine consumers. In a study conducted in Iraq, it was found that there were several obstacles to prescribing generic medicines such as doctors' unwillingness to prescribe generic medicines, mix-up over different brands and presence of counterfeit medicines (Sharrad & Hassali 2011). Majority of the participants conveyed that they would accept generic substitution with the doctor's approval whereas a few would accept on recommendation of chemist. To overcome gap in consumers' knowledge in Iraq, there is a need for education about the benefits of generic medicines as concluded in the study.

In a study conducted in Turkey (Toklu et al 2012) to assess knowledge and attitudes towards generic medicines of patients, pharmacists and physicians, it was found that patients, pharmacists and doctors have insufficient knowledge about generic medicines. It was seen there is no association between acceptance of generic drugs and demographics such as age, gender, and income (excluding education). However, a negative association was found between acceptance of generic drugs and level of education, i.e., acceptance of generic substitution is unlikely with more highly educated patients.

A strong evidence as evaluated in the literature review has been seen that both doctors and chemists have an important role to play in promoting generic drugs and its acceptance by patients [4, 9, 11, 12, 13, 29, 30, 34, 36, 40]. In Spain and Portugal the vast majority of patients surveyed stated that on recommendation of their physicians they would accept unbranded medicines. The majority of patients in Finland & New Zealand would take generic medicines based on recommendation of a pharmacist. Majority of those surveyed in Malaysia, New Zealand, Norway and Japan indicated acceptance of generic medicines on recommendation of a physician or pharmacist. It seems more than chemists, doctors have an important role in convincing patients for use of generic drugs in some countries. In the UK it was found variation in the percentage of patients for acceptance of generics if recommended by medical consultant/hospital (75.3%), general practitioner (33.3%), pharmacist (24.8%) and nurse (20.8%). However, physicians and pharmacists can also decrease use of generic medicines by writing, dispensing or recommending only branded medicines which could be an obstacle to acceptance of generic medicines [1, 4, 9, 10, 12, 13]. For example, in one study it was found that the main reason for patients not using generic medicines is due to prescribing of branded medicines by physicians [13].

Negative perceptions about generic medicines compared with their branded equivalents, are being held by a majority of doctors, pharmacists and lay people who perceive generic medicines low in quality, hence less safe and less effective. Probably such attitudes serve as barriers to the extensive use of generic drugs. A review of observational studies based on 52 articles on perceptions of generic medicines amongst population, physicians and pharmacists was conducted (Colgan et al 2015). The publication included data from 27 countries from 1987 to 2015. On effectiveness, a majority of general population 35.59% believed generic medicines were less effective than their branded equivalents compared to doctors 28.68% and pharmacists 23.60%. On quality, minimum 25% from each group (pharmacist 33.39%, physicians 28.04%,

general population 25.11%) believe generic medicines are of lower quality than branded medicines. On safety, a greater proportion of doctors (28.54%), pharmacists (25.44%) and general population (17.97%) perceived generic medicines less safe compared with branded medicines.

With an aim to build confidence among doctors, pharmacists, and consumers, the government must promote awareness on quality of generics. In a study on price and quality of medicines to assess the generic and the equivalent brand, it was found unexpectedly that price difference for generics to patient was not high but margins to chemists were very high for branded generics. The study highlights the need to change policy on drug pricing, control mark-ups, conduct tests and extensively advertise quality of generics (Singal 2011).

Concerns amongst resident doctors about efficacy safety and availability of generic medicines are major reasons for preferring brand medicines. In a study (Zaverbhai et al 2017), conducted at a tertiary care teaching hospital in Gujarat, it was found that the doctors preferred brand over generic medicine due to reasons such as concern about efficacy (100%), concern about safety (61.57%), poor availability of generic medicines (75.85%), adequate information not available (33.06%) . Majority of respondents did not agree to substitution of brand medicine with a generic one by pharmacist due to doubts about quality, effectiveness and safety of generic medicines and hence, may not desire substitution of former.

Patients', doctors' and pharmacists' perceptions mostly favoured branded medicines despite comparable quality of generic and branded variants of the medicines found in testing. Negative perceptions on quality of generic drugs and doctors' oriented promotional activities by pharmaceutical companies for branded drugs is leading to choosing expensive branded drugs in the private sector (Aivalli et al 2018).

Doctors prefer branded medicines over generic medicines. In a study (Tripathi & Bhattacharya 2018) undertaken to assess experience and attitude of patients who were consuming generic drugs purchased from Jan Aushadhi stores in a Tertiary Care Hospital in Northern India, it was found 72% of the participants heard about generic medicines and 65% could differentiate between branded and generic medicines. Despite 67% agreed that generic medicines are cheaper than branded medicines, only 35% of them preferred to buy generic medicines as 61% of them believed that generic medicines are of low quality compared with branded medicines.

Most (64%) of the patients never asked his/her doctor or pharmacist (59%) to prescribe/ distribute generic medicines. According to patients (45%) doctors preferred branded medicines over generic medicines. The limited availability, poor knowledge and attitude of patients regarding quality of generic drugs hinder its widespread acceptance in prescribing and dispensation.

A good percentage of doctors were well aware of generic medicines' usage. In a study to explore doctors' perceptions and understanding (knowledge, attitude and practice) about generic medicines at a tertiary care hospital in North India (Gupta et al 2018), it was concluded that 62.9% doctors agreed to the fact that generic medicines were intended to be interchangeable with a branded medicine. 77.5% of doctors had awareness that manufacturers of generic medicines need to conduct studies to show bioequivalence between the generic medicine and their branded counterparts. 88.8% of the doctors agreed that importance of generic medicines should be taught in early part of internship. 80.9% doctors were of thinking that outcome of treatment may not change in switching from a brand-name to generic drug. However due to concerns expressed by a certain fraction of participants, further effort is required on how interventions both for doctors and public may lead to increase in the awareness and acceptability of generic medicines.

In an article 'Prescribing generics: All in a name' (Roy and Rana 2018), it was highlighted the major reason why doctors may not prescribe unbranded generic medicine is the lack of confidence of physicians and patients in the quality of generics. Aggressive promotion of branded generic medicines by the pharmaceutical companies further aggravates the problem. Lack of Good Manufacturing Practices by pharmaceutical companies has been a major concern regarding safety and effectiveness of generic drugs.

The fostering of close relationship between doctors and pharma companies managed through medical representatives (MRs) has been known the world over which works both ways – companies assisting doctors increase in their knowledge of company's product and doctors giving feedback to companies to develop new and more effective medicines. Such collaboration benefits patients and society through improved healthcare. In a study on customer loyalty (Bachheti & Saklani 2013), it was found that both rewards to doctors and striking of close relationships between doctors and MRs influence doctors' prescription.

In a study to assess awareness and attitudes of doctors towards bringing down the cost of medicines (Billa et al 2014), it was found that high proportion of government doctors (GDs) and private doctors (PDs) at 97% and 72% respectively are concerned with high cost of medicines. GDs and PDs at 80% stated that more than cost, safety and efficacy were more important. A majority of GDs (71%) and PDs (65%) knew about the various methods in bringing down the cost. Drugs were graded according to cost by 24% of GDs and 65 % of PDs. High proportion of GDs (94%) and PDs (73%) stated that life-saving drugs should not be covered under patent protection. Stepwise introduction of generic medicines by 64% of GDs and 10% of PDs and the use of generics by 20% of GDs and 10% of PDs was stated. Factors preventing use of generics were due to narrow therapeutic index drugs (43.5%) and fear of inferior quality (38.5%).

The generic drug can considerably bring down the cost involved in the treatment but without compromising efficacy and safety. The generic drug must prove to be bioequivalent with their branded counterparts. The possible and immediate effect of this decision will be that the unethical or commission based prescription by the doctors will be hampered [41].

Negative perceptions about generic medicines compared with their branded equivalents are being held by a majority of doctors, pharmacists, and lay people who perceive generic medicines inferior in quality, may cause side effects, hence less safe and less effective [20]. Physicians and pharmacists, along with activities aimed at educating patients, have an important role to play in the promotion & recommendation of generic medicines more often. Research suggests that the majority of patients learn about generic medicines from healthcare professionals which is critical to patients' decision to accept generic medicines [4, 34].

Numerous studies have been carried out globally exploring perception, knowledge, attitude, practice etc. of generic medicines amongst population, patients, pharmacists and prescribers of generic medicines.

Most of the studies conducted are in developed countries, further studies mostly in developing countries are required. Considering demographics and other factors, the need for cost savings and the decision making process for prescribing generic medicines is more in developing countries.

Most of the studies conducted to assess perception, knowledge, attitude etc. are focused on patients, customers and population however, limited studies are available focused on doctors. The studies available on perception of doctors towards generic medicines, largely limited to few tertiary care hospitals in India were mostly pilot in nature but were able to offer initial findings and valuable understandings to encourage further research in this under-researched area.

DISCUSSION

If doctors start to prescribe more and more of medicines in generic names will it solve the problem of reducing the cost of medicines to patients? The question needs to be looked at from different perspectives.

Let's look at with the perspective of patients first who incur high out-of-pocket expenses. On getting prescription in generic medicines, the next question is from where will the patient have the prescription filled for generic medicines? Presently generic drugs (without any brand name) are available at Jan Aushadhi stores where supplies besides its numbers and spread, availability of range of products and access to such stores have been a constraint. It has also been found that patients, customers and general population hold negative perception about generics (Colgan et al, 2015). So, what seems critical is patients' acceptance of generics medicines and generic substitution.

Better communication between healthcare professionals and patients may help in educating patients about generic medicines and its acceptance (Sharrad & Hassali 2011; Alrasheedy et al 2014). But then why doctors should be doing this? If we look at it from doctors' perspective, it is largely believed that possible commercial orientation of some doctors supplemented with preferential promotion of branded medicines by pharma companies involving benefits to doctors is a major hurdle in prescribing generic medicines.

Quality of generics (efficacy & safety) has also been a major factor for doctors not prescribing generics (Zaverbhai et al 2017; Aivalli & Annie et al 2018). The question is how doctors' perception with relation to generic medicines that they may not meet standards and that they may be ineffective can be addressed? There are many pharmaceutical companies in India manufacturing and distributing products regionally and nationally. What system need to be put in place that would ensure all the generics are of standard quality providing enough confidence

to doctors in prescribing generics? There has been concerns amongst patients, doctors and chemists on quality of generic medicines. If the patients do not get satisfactory relief from illness with the use of generic medicines, doctors run the risk of losing patients and negative publicity. With quality concerns on generics why would doctors prescribe them (generics)? Eventually, will the patients whose responsibility for curing the illness rests on doctors, be benefitted with the dispensation of generic medicines?

Next is the issue of the chemist. As per government directive, the doctors are supposed to write prescription in generic name but it is the chemists who will dispense based on their possible bias - what is available and what is more profitable to them. Let's look at it from the chemists' perspective, chemists keep stocks of wide ranging products of branded medicines. Some of the products though in branded form are being pushed by pharmaceutical companies through chemists who are being offered heavy discounts. Interestingly, heavy discounted products to chemists are not being promoted to doctors and some of the companies have two brands of the same molecule, one being promoted to the doctors and the other being offered at heavy discount to chemists. Why the pharma companies are doing this is not so far clear. This offers chemists much more lucrative proposition to substitute branded medicines with unknown substitutes (another equivalent branded medicines) which are treated as generics. The motive of chemists may often be commercially driven, obviously maximization of profit may take precedence over benefits to patients. In light of current scenario, decision on dispensation of brand will shift from doctors to chemists which may not meet with the objective of the government's directive.

Low margins to chemists allowed on low priced generics (without any brand name) currently available through Jan Aushadhi stores, may not make it a commercially viable business for a chemist considering fixed and variable overheads in running a pharmacy shop with a qualified pharmacist. Then why would a chemist promote generic medicines?

Another issue concerning dispensation of medicines at chemist shops may be the unavailability of qualified pharmacist at few shops. There have been instances of chemist shops having been sealed or licenses suspended by regulatory authority for being run without a pharmacist. In light of this, will the unregistered person or an unqualified person the so called pharmacist may be in few chemist shops, will be in a position to play his or her role effectively and responsibly attending to patients in the dispensation of generic medicines?

Perspective of pharma companies in the marketing of generics is another area that needs to be looked at. In addition to manufacturing and distribution, brand management strategy and promotion has been an area of focus of many leading companies to obtain the prescription by its brand name. The strategy on brand management enables companies to differentiate products from others. The question arises, how a pharma company can differentiate products in generic names? In other words, how generics need to be promoted to doctors? Prescription in generic names will be filled by chemists who will like to dispense those products on which they can make more money and not necessarily the generic medicine being promoted of a particular company.

The role of MRs have been recognized in developing closer relationships with doctors which influences them in prescribing brands (Bachheti & Saklani 2013). Apart from getting doctors' support for prescribing brands, the collaborative approach between doctors and pharma companies assist each other in inventing new and improved medicines for the wellbeing of the society. MRs establish communication channel between them. The role of MRs may not be of much worth if doctors were to prescribe generic medicines. What would be the communication channel between doctors and pharma companies then that needs to be pondered over?

There are many questions that arise with the directive of the government asking doctors to prescribe generic medicines. It is important to develop a deeper understanding on the challenges involved in prescribing generic medicines. Doctors being the key decision makers in prescribing medicines are the ones whose inputs are vital.

RESEARCH FRAMEWORK OF THE STUDY

Analyzing the doctor's behavior in prescribing generic medicines is essential to developing an understanding with an aim to explore the key underlying factors for low usage of generic medicines in the country. An honest explanation for the fact that generic medicines have low acceptance could be that doctors lack knowledge and or have negative attitude about generic medicines.

To understand doctor's prescription behaviour we use Tri-component attitude model, which includes Cognitive-affective-conative processes of decision making. Cognitive-affective-conative are psychological process model for humans. In this, cognitive term shows thinking ability, understanding capacity and decision-making skills of a person. Cognitive psychology

is interested into read mind of person. Affective is another psychological term related with emotions, motivation of doctors. Emotions of a person may be positive or negative depends on the situation and depends on persons thinking. Motivation and demotivation comes under affective psychology. There are many ways to motivate doctors like engagement (seminars and conferences) and inducements (incentives, gifts and holiday trips). Conative means any natural tendency, impulse or directed effort. Conative is one of three parts of mind along with affective and cognitive. Conative shows action on any thought process which differs from person to person.

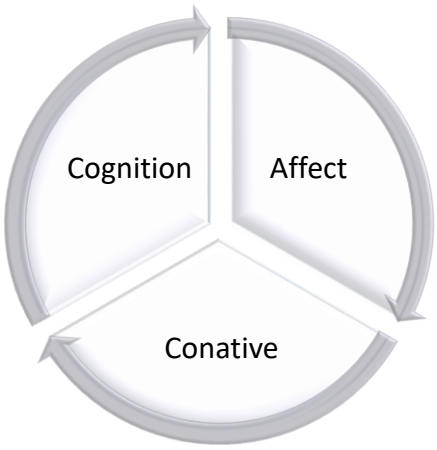

Figure 1: A Simple Representation of the Tri-component Model of Cognitive-affective-conative processes of decision making

The research work will be focused on analyzing the doctor's behavior using three dimensions, i.e., cognitive, affective, and conative (Singh KR et al 2016; Simone Dohle & Michael Siegrist 2014). The study will examine different likely predictors of generic medicine acceptance and use and aims to identify the strongest cognitive and affective drivers of generic drug evaluations. Finally, the results may explain why generic medicine use is not much. Additionally, some of the significant insights could help in developing marketing strategies or interventions aimed at increasing usage of generic medicines to bring down healthcare costs.

RATIONALE OF THE STUDY

With the small market share of generics in India, the study aims to examine factors that influence doctors in North India (Dehradun) in prescribing generic medicines as doctors being the key decision making agents in the prescription decision.

Doctors are independent prolific prescribers in a primary, secondary & tertiary healthcare centres. Data regarding knowledge, attitude and practice of Indian prescribers towards generic

drugs is limited. Hence, the present study is aimed to evaluate knowledge, attitude and practice of doctors in a primary, secondary and tertiary care hospitals in government and private hospitals in Dehradun District, Uttarakhand regarding generic medicines to identify factors that hinders or encourages prescription of generic medicines.

A majority of Indian population (nearly 68%) has either inadequate or no access to essential medicines according to WHO report. Additionally, dispensation of free medicines in public healthcare services has dropped from 31.2% to 8.9% for inpatient and from 17.8% to 5.9 % for outpatient over the last two decades, according to a 2011 PHFI study. Out-of-pocket expenses make up 62% of healthcare costs in India (USA, UK 20%, BRICS countries about 20-25%).

The study will be novel in the sense that apart from assessing level of understanding and attitude amongst the doctors of various specialties at primary, secondary and tertiary healthcare centres, it would explore, identify and address other contentious issues that doctors may have in prescribing generic medicines.

The study also intends to explore the marketing aspects of generic medicines that the pharmaceutical companies need to take into consideration on the basis of the outcome of the analysis of the study.

The study is of national importance that addresses the issue of low generic prescriptions despite high out-of-pocket expenses and majority of the population living in the rural area with low income.

RESEARCH OBJECTIVES

The research objectives for the study include:

1. To ascertain factors that have influence on doctors in prescribing generic medicines.
2. To find out relationship between factors and prescription of generic medicines
3. To compare level of influence associated with different factors on doctors at different healthcare delivery points – primary, secondary and tertiary healthcare centers.
4. To evaluate if acceptance and use of generic medicine could be explained by Tri-component Model of Cognitive-affective-conative processes of decision making.
5. To bring forth suggestions that may lead to increase in prescribing of generic medicines.
6. To suggest marketing aspects of generic medicines that the pharmaceutical companies

need to take into consideration based on the outcome of the analysis of the study.

HYPOTHESIS

Hypo 1	Knowledge of generic medicines plays a significant role in influencing doctors in prescribing generic medicines
Hypo 2	Attitude towards generic medicines plays a significant role in influencing doctors in prescribing generic medicines
Hypo 3	There is no difference in knowledge of generic medicines amongst doctors at primary, secondary and tertiary healthcare centres
Hypo 4	There is no difference in attitude amongst doctors at primary, secondary and tertiary hospitals
Hypo 5	There is no difference in practice of prescribing generic medicines amongst doctors at primary, secondary and healthcare centres.
Hypo 6	Knowledge (cognitive) of generic medicine and Attitude (affect) towards generic medicine have significant influence (conative) on doctors prescribing generic medicine.

RESEARCH METHODOLOGY

Research Design

Basic research type is descriptive and cross-sectional

Data Sources

Both primary and secondary data will be used. The major type of information to be used will be primary data which will be collected by survey. The literature review is secondary data type of which the sources include websites, periodicals, magazines, newspapers etc.

Data Collection Methods

The survey research method will be employed for collecting the primary data. This will be taken care by designing of the questionnaire which will be self-administered.

The questionnaire will include all measures regarding factors such as knowledge, attitude and practice of doctors at primary, secondary and tertiary healthcare centres.

Sample Plan and Size

Universe- Includes doctors at primary, secondary and tertiary healthcare centres.

Elements: Doctors in Dehradun district (Indian Medical Association membership list of doctors)

Sample Unit – Doctor

Area of Survey – Dehradun District

Dehradun is a capital city of Uttarakhand where medical infrastructure is well developed has numerous specialty and super-specialty hospitals and is the major medical consultancy hub of the state. Rishikesh and Vikasnagar too have specialty medical care available, but limited to the city of Dehradun.

The medical infrastructure includes 4 medical universities (2 government and 2 private), leading government & private hospitals, primary health care centers and independent practicing doctors.

Sample Size – 200

Calculations for sample size (n) is determined as follows:

$n = (Z_{\alpha/2})^2 pq/d^2 = [(1.96)^2 * (50^2)]/5^2 = 384$

$d = Z_{\alpha/2}\sqrt{[(1/n + 1/N)pq]} = 1.96\sqrt{[\left(\frac{1}{384} + \frac{1}{671}\right) * (50 * 50)]} = 6.2671$

Where

N = population size,

p = 50% unknown,

q = 50% (100 – p), d = 5%,

α= 5% level of significance.

Minimum sample size

$= (Z_{\alpha/2})^2 pq/[d^2 + (Z^2_{\alpha/2}\, pq/N)] = 1.96^2 * 50^2/[6.2671^2 + (1.96^2 * 50^2/671)] = 179$

Sampling Procedure – Systematic Random sampling technique is to be followed.

Data Analysis

Data collected will be analyzed to make it meaningful. Data analysis would involve entering data into computer files, inspecting it for errors as a first step in data cleaning followed by running tabulations and various statistical tests. Data analysis will involve descriptive analysis with the use of tests such as t-test, co-variance, regression analysis, ANOVA followed by inferential analysis. Data analysis will involve use of software SPSS.

TENTATIVE CHAPTER PLAN

Chapter 1: Introduction

Chapter 2: Review of Literature

Chapter 3: Research Methodology

Chapter 4: Data Analysis and Interpretation

Chapter 5: Discussion and Conclusion

LIMITATIONS

1. This study focuses on the subjects' responses and not their actual behavior while prescribing medicines.
2. This study limits itself to select district which may limit the extrapolation of findings to the entire country, but the study would be appropriate to point out directions for promotions aiming at the expansion of the acceptance and use of generic medicines.

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